Transfemoral endovascular repair of abdominal aortic aneurysm using the endovascular graft system device

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Introduction

Approximately 40 000 patients undergo elective abdominal aortic aneurysm repair in the USA each year. In spite of this, approximately 15 000 patients die from ruptured abdominal aortic aneurysm on an annual basis. This makes ruptured abdominal aortic aneurysm the fourteenth leading cause of death in the USA. Efforts to reduce this continued mortality risk from aneurysm rupture would include the introduction of population screening with ultrasound and the willingness to offer elective aneurysm repair to good risk patients with aneurysms both larger and smaller than the conventional 5.0 cm diameter cut-point.

Currently, elective repair of abdominal aortic aneurysm can be done with a mortality of <3.0% in centres of excellence. However, community-wide studies have shown that mortality for elective abdominal aortic aneurysm repair is probably in the range of 10–14% (Veith *et al.*, 1991). This relatively high mortality rate has an adverse effect on the risk/benefit ratio for operating on small aneurysms.

The introduction of the concept of endovascular repair of abdominal aortic aneurysm may alter the current scepticism concerning repair of small abdominal aortic aneurysm as well as making repair of larger aneurysms simpler and safer.

Through the years, there have been several experimental attempts at endovascular aneurysm repair (Cragg *et al.*, 1993; Balko *et al.*, 1986). With the first documented clinical application of this technique by Parodi in 1991, the concept became a reality (Parodi, Palmaz and Barone, 1991). Parodi has accumulated a wide experience, primarily in Argentina, but also in other centres around the world as his device has been applied on a compassionate use basis.

Several other investigators have developed similar techniques, and the first device to receive Federal Drug Administration (FDA) approval for clinical investigation in the United States was the endovascular graft system (EGS) system introduced by EndoVascular Technologies. A Phase 1 trial was begun in the USA with the first implantation performed at UCLA Medical Center on 10 February 1993. As Phase 1 implant patients rapidly accumulated and were found to be successful, we are now making preparation for Phase 2, which will be a prospective randomized trial comparing conventional repair with endovascular repair.

The objective of this chapter will be to present a detailed description of the technical aspects of implantation.

Patient evaluation

At the present time, the current graft configuration is suitable for those patients whose aneurysm is limited to the infrarenal abdominal aorta and can be repaired with a tube graft implantation. The anatomic requirements include a sufficient length of neck between the lowest renal artery and the beginning of the aneurysm, and a sufficient neck length at the distal extent of the aneurysm, proximal to the iliac bifurcation. The diameter of the proximal and distal neck must not exceed 24 mm, which is the current upper limit of available graft size. It is preferable to have an occluded inferior mesenteric artery. If patent, there should be no evidence that the inferior mesenteric artery provides collateral blood flow to a compromised coeliac or superior mesenteric artery circulation.

Evaluation of a prospective patient includes a computed tomographic (CT) scan. This provides information concerning the presence of proximal and distal aneurysm neck, neck diameter, and aneurysm size. At the present time, the next step involves obtaining a magnetic resonance imaging/magnetic resonance angiography (MRI/MRA) of the abdominal aorta. This provides a good estimate of what an angiogram would show and permits us to make a final decision before committing the patient to an invasive angiogram. If the first two tests demonstrate suitable anatomy, the final step is a contrast angiogram performed with an angiogram catheter that has radio-opaque marks at 1.0 cm intervals in order to achieve an accurate measurement of both the length and diameter of the graft that will be required.

Once it has been determined that the patient has an aneurysm of appropriate anatomic characteristics, preparation is made for operation. Repair of the aneurysm must be performed in an operating room by a team that is prepared to convert the operation to a conventional open repair should this become necessary. General anaesthesia is employed. The patient's abdomen and both groins are prepared and surgically draped for either transfemoral repair or transabdominal conventional repair of abdominal aortic aneurysm. Surgical nurses are scrubbed in the usual manner and instrumentation is available as for conventional operation.

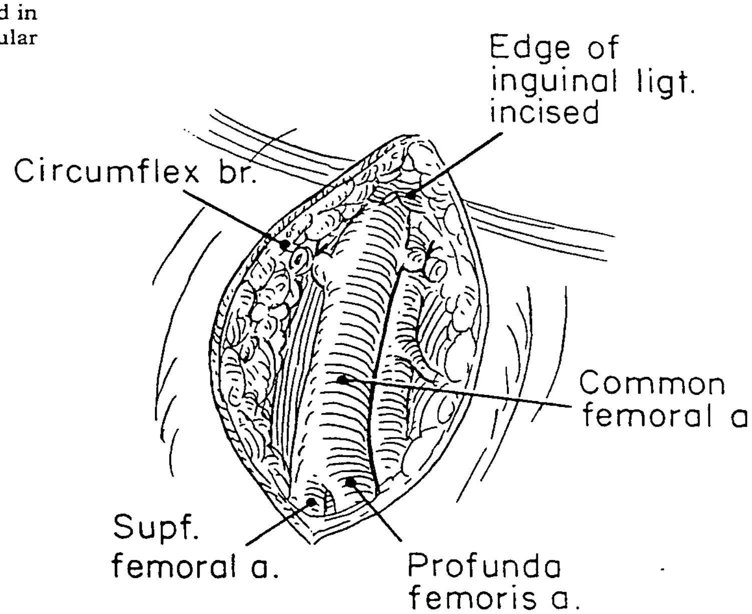
We have not found it necessary to have a specially equipped operating room for these procedures. A Skytron 3100 operating table has been quite satisfactory. The mechanics of this table permit horizontal sliding of the tabletop to its full length in order to provide adequate space beneath the table top for the C-arm of a fluoroscopic unit. We have utilized a portable OEC-Biasonics C-arm that has digital imaging and road-map capability. Since this instrument is portable, it can be used in any operating suite for most purposes, including endovascular graft repair.

1a & b

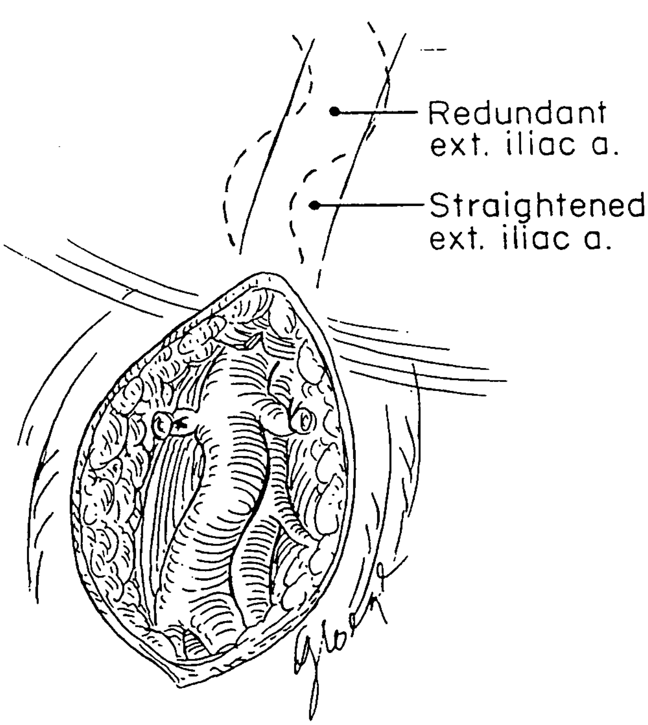
The common femoral artery is exposed through a vertical incision (*1a*). Selection of either the right or left femoral artery is based upon the size and configuration of the iliac artery and its relationship to the aorta in order to make passage of the catheter system as smooth as possible.

The edge of the inguinal ligament is incised. The circumflex branches are divided in order to provide good mobilization of the common femoral artery.

If there is significant tortuosity or redundancy of the iliac artery, this can be straightened out by bluntly mobilizing the external iliac artery and drawing it into the operative field (*1b*).



1a

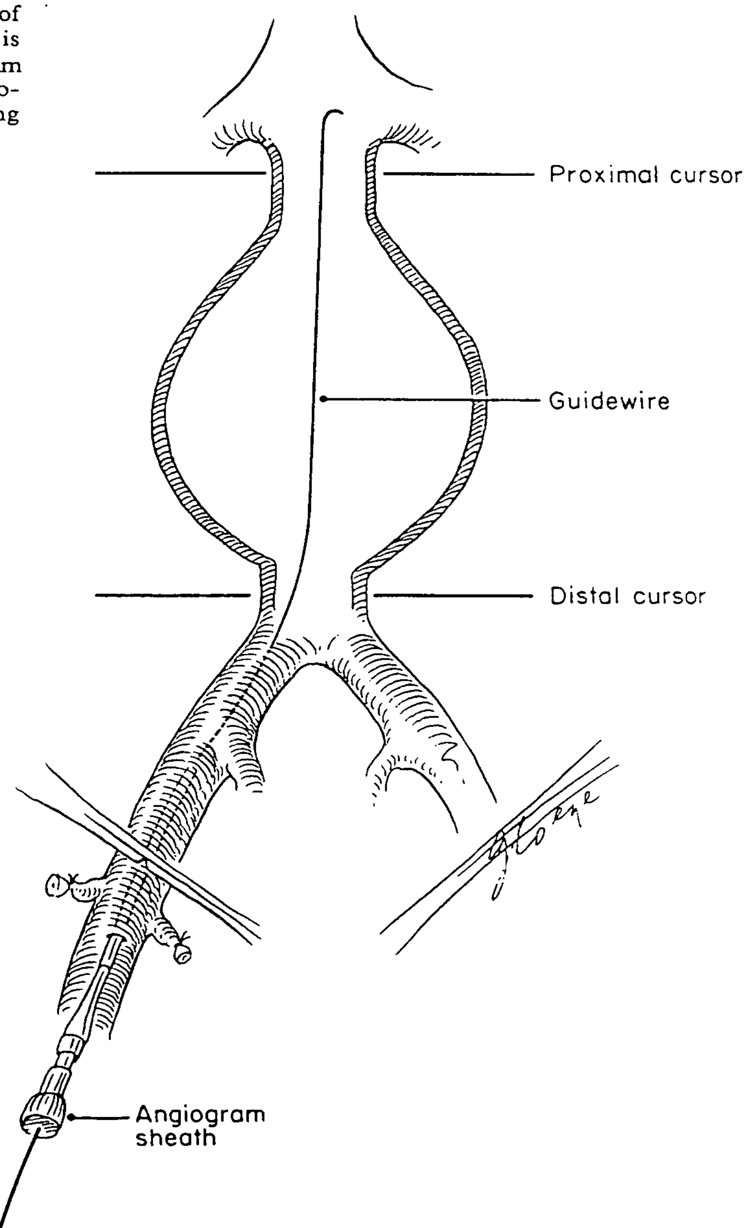


1b

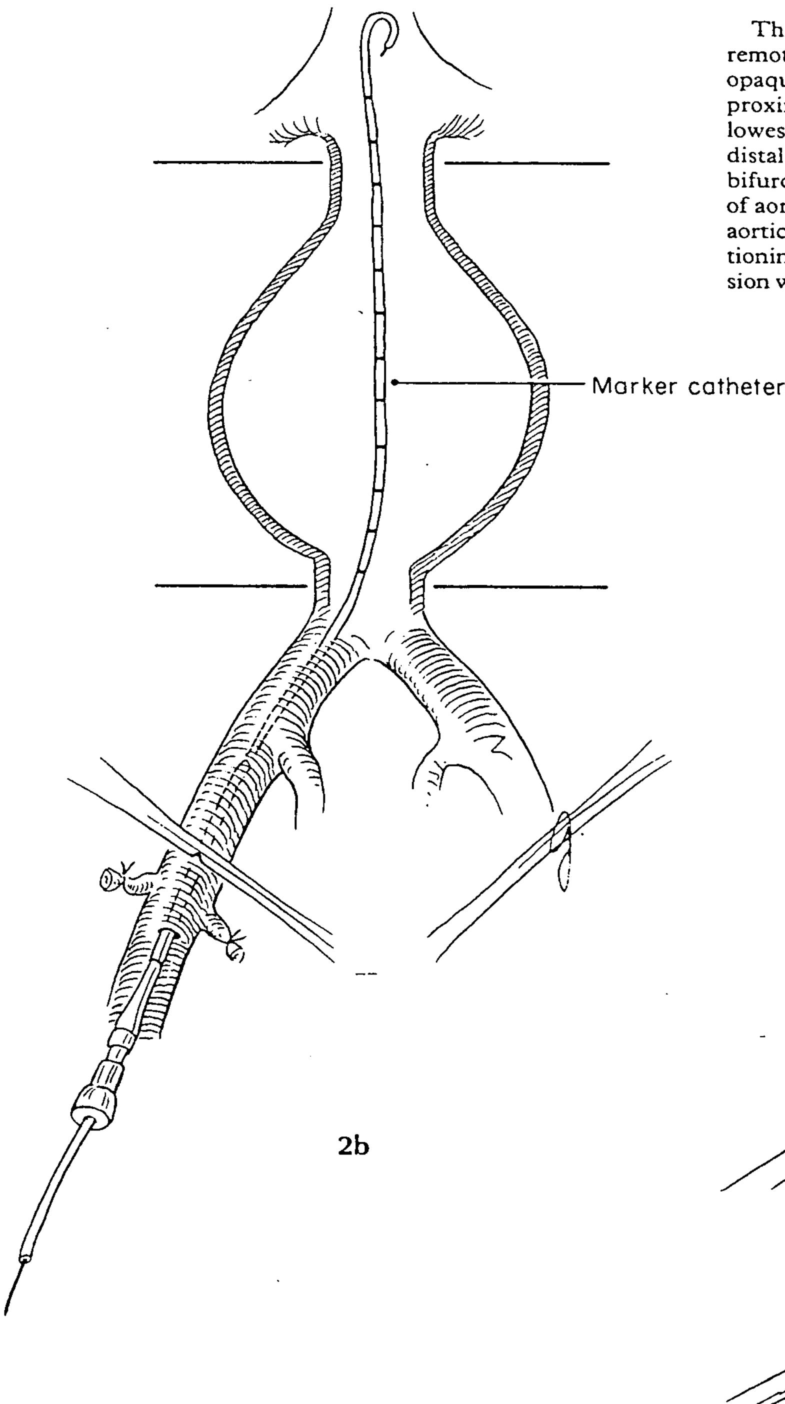
2a & b

The femoral artery is punctured with a 16-gauge needle, and a guidewire is placed through the lumen of the needle (*2a*). The needle is withdrawn, and a 9 French angiogram sheath is passed over the guidewire into the femoral artery and advanced into the external iliac artery under fluoroscopic guidance.

A pigtail angiogram catheter with 1.0 cm radio-opaque marks is then advanced (*2b*) over the guidewire, through the sheath, and into the aorta under fluoroscopic guidance. The catheter tip is manipulated through the aneurysm and positioned in the vicinity of the T12-L1 interspace. A test injection is made with contrast material to determine that the catheter is above the renal arteries. The fluoroscopy tube is appropriately positioned to be certain that the entire extent of the abdominal aorta from renal arteries to iliac bifurcation is centered within the fluoroscopic field of image. An aortogram is then obtained utilizing a pressure injector, and the aortographic image is frozen on the screen using the roadmapping mode.



2a

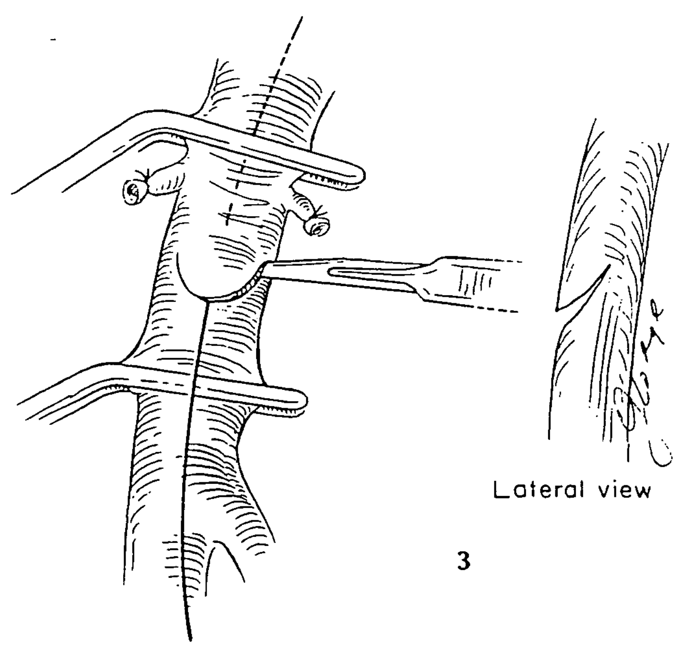


2b

The patient has been positioned on a board that permits the remote movement of horizontal cursor lines that are radio-opaque. The superior line is moved into the optimal point for proximal graft deployment. This should be just below the lowest renal artery. A distal cursor line is positioned in the distal neck of the aneurysm as far proximal from the aortic bifurcation as possible. Ideally, there should be enough length of aorta between the point of distal graft deployment and the aortic bifurcation as possible. This will permit the best positioning of the balloon catheter in order to permit full expansion without encroachment upon the orifice of the iliac artery.

3

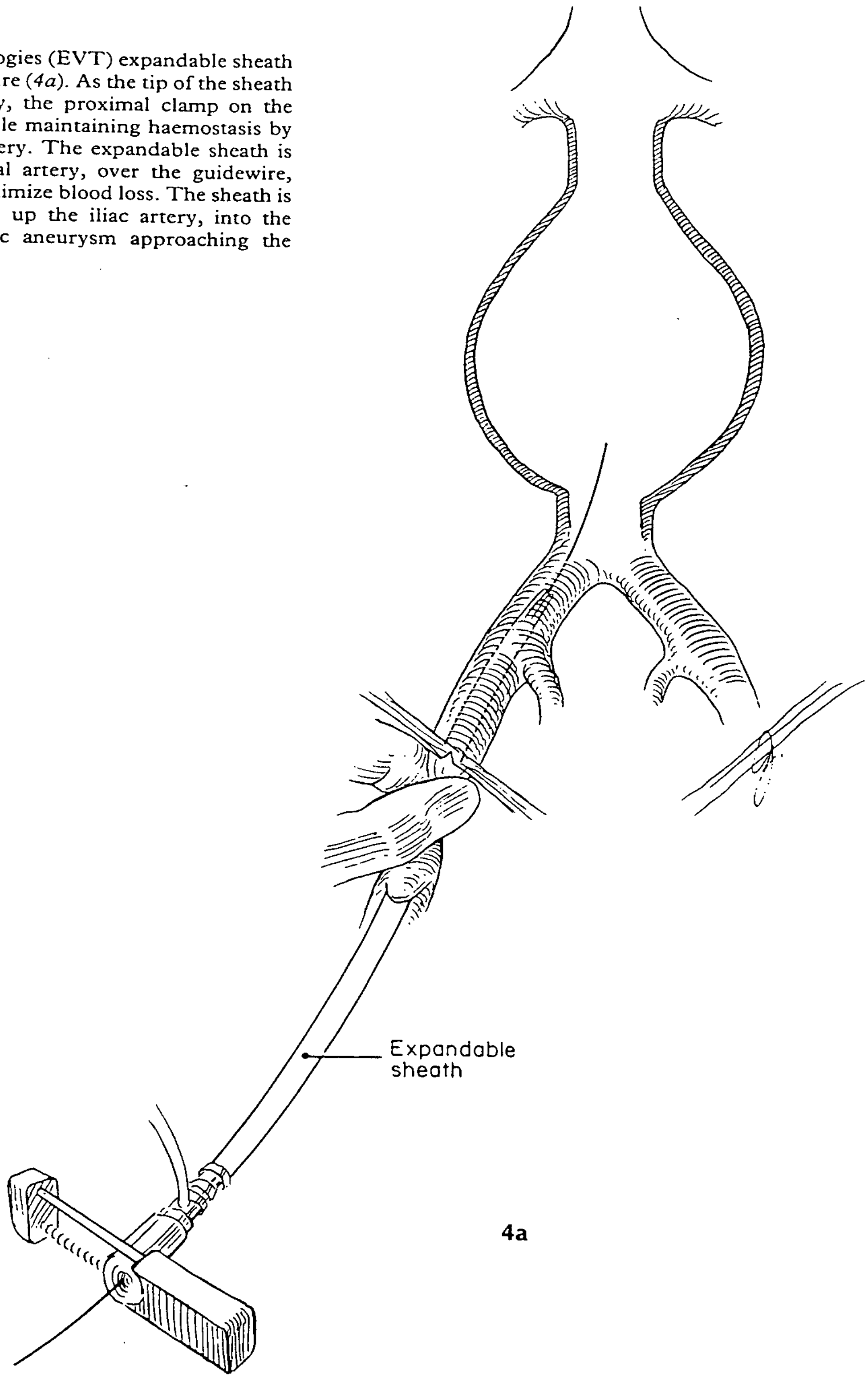
The patient is then systemically heparinized with 5000 units of heparin. The femoral artery is clamped proximally and distally over the guidewire after the angiogram sheath is withdrawn. An oblique incision is made in the femoral artery encompassing the angiogram puncture site. This permits a 'fish mouth' opening into the artery and provides an optimal aperture for placement of the sheath.



3

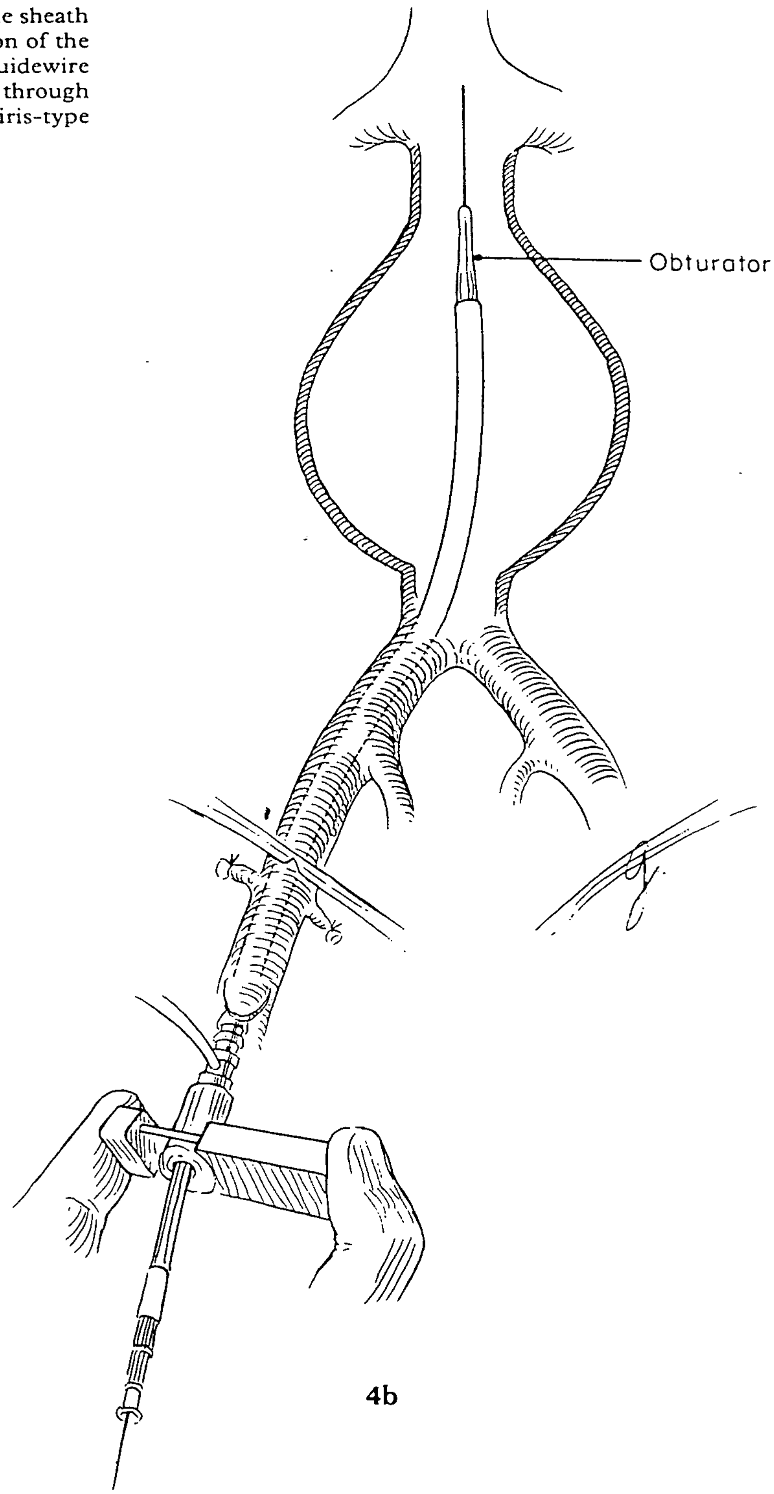
4a & b

A 28F EndoVascular Technologies (EVT) expandable sheath is then passed over the guidewire (*4a*). As the tip of the sheath approaches the femoral artery, the proximal clamp on the femoral artery is removed while maintaining haemostasis by digital compression of the artery. The expandable sheath is then inserted into the femoral artery, over the guidewire, using bi-manual control to minimize blood loss. The sheath is advanced over the guidewire, up the iliac artery, into the aorta, and through the aortic aneurysm approaching the proximal neck.



4a

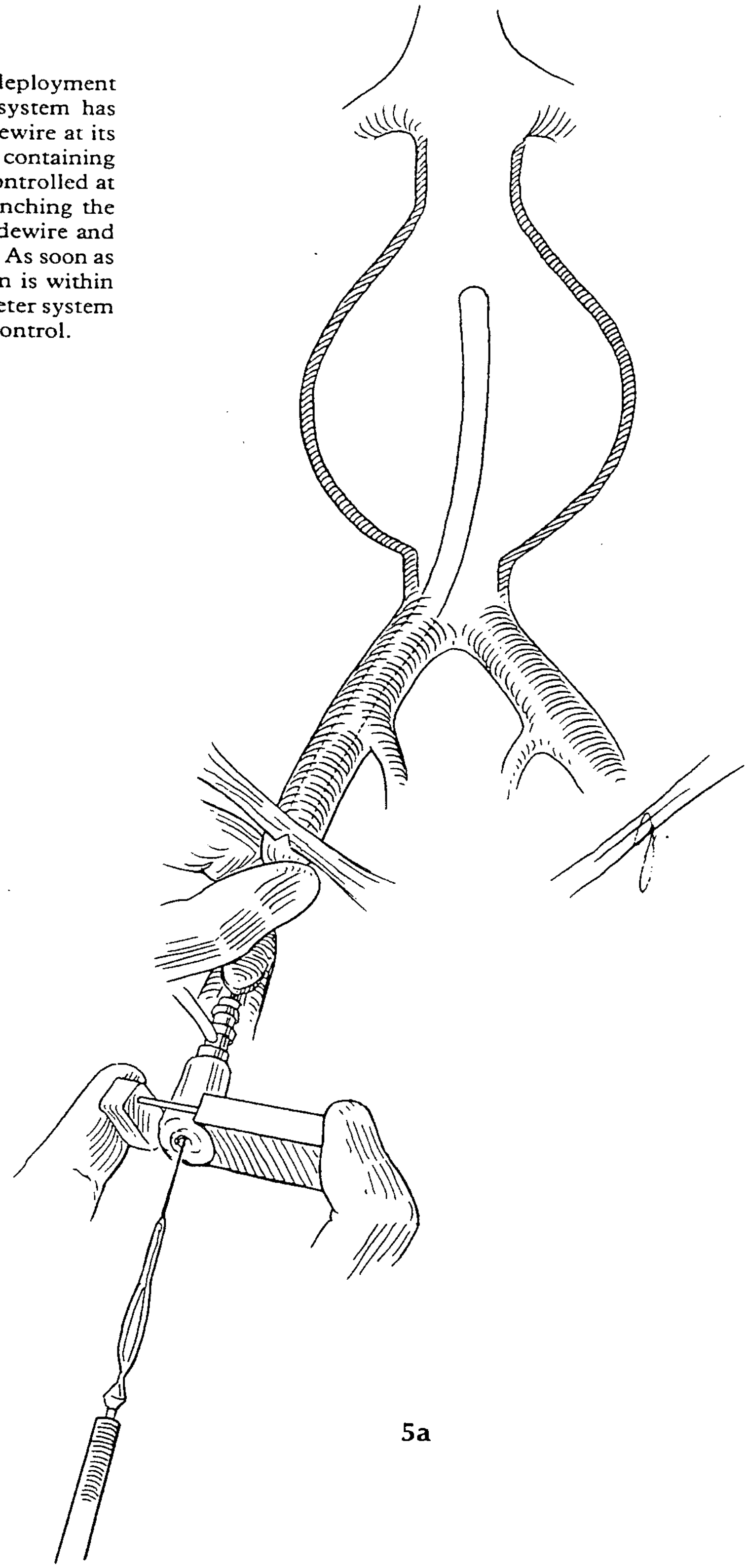
Once the sheath is in place, the obturator within the sheath is fully advanced in order to expand the distal portion of the sheath to its full diameter (*4b*). The obturator and guidewire are then removed from the sheath, and backbleeding through the sheath is controlled with a manually adjustable, iris-type diaphragm.



4b

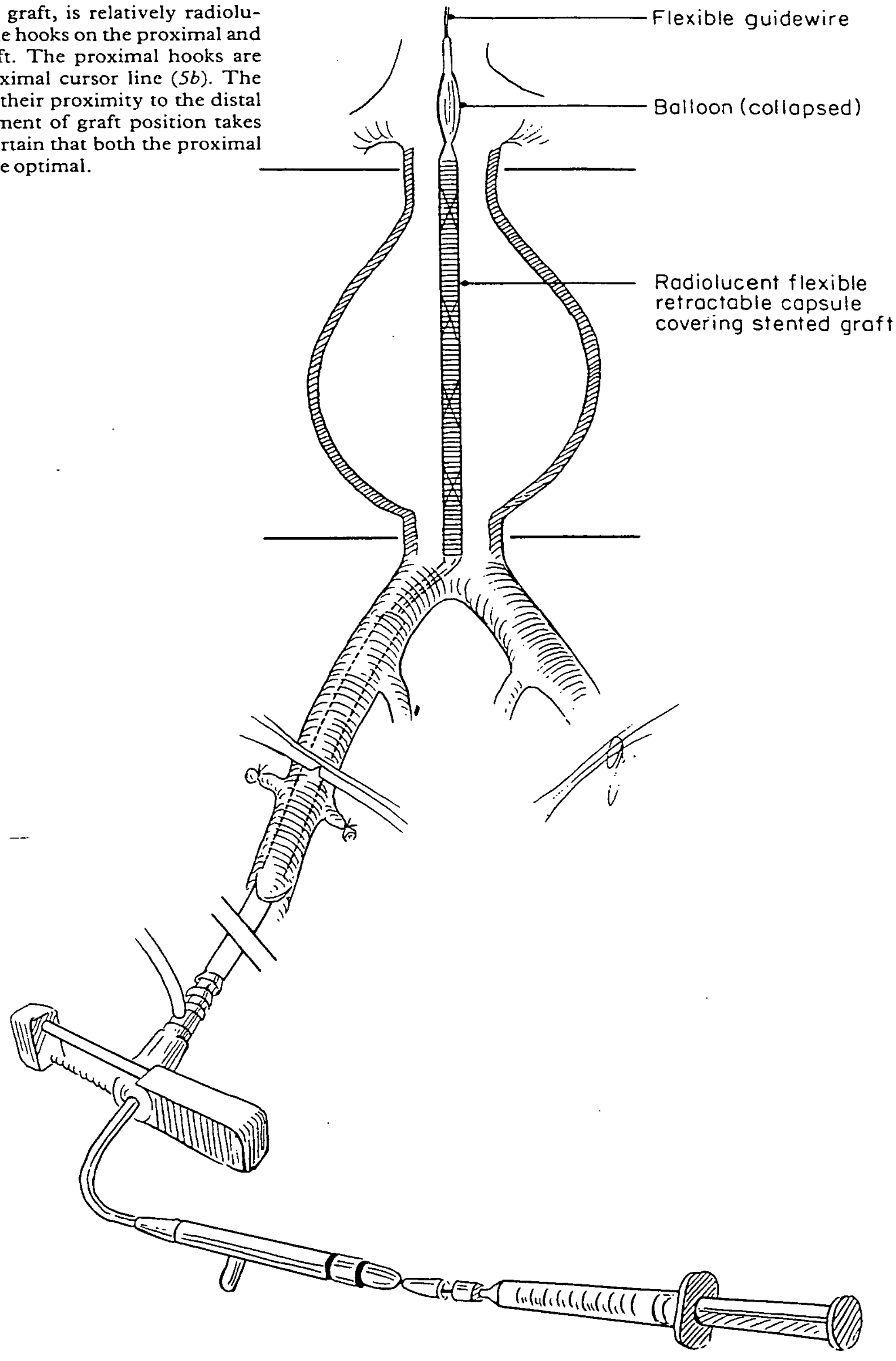
5a & b

Preparation is then made for insertion of the graft deployment catheter system (*5a*). The deployment catheter system has several components, which include a flexible guidewire at its tip, an expandable balloon, and a flexible capsule containing the graft. This co-axial system is then remotely controlled at the handle by the operator. With the assistant pinching the sheath, the iris diaphragm is opened, and the guidewire and co-axial catheter system is inserted into the sheath. As soon as the capsule portion of the catheter delivery system is within the sheath, a haemostatic seal is achieved. The catheter system is then advanced up the sheath under fluoroscopic control.



5a

The capsule, which covers the graft, is relatively radiolucent and permits the imaging of the hooks on the proximal and distal stented portion of the graft. The proximal hooks are then positioned opposite the proximal cursor line (*5b*). The distal hooks are then checked for their proximity to the distal cursor line. Final vertical adjustment of graft position takes place at this time in order to be certain that both the proximal and distal points of deployment are optimal.

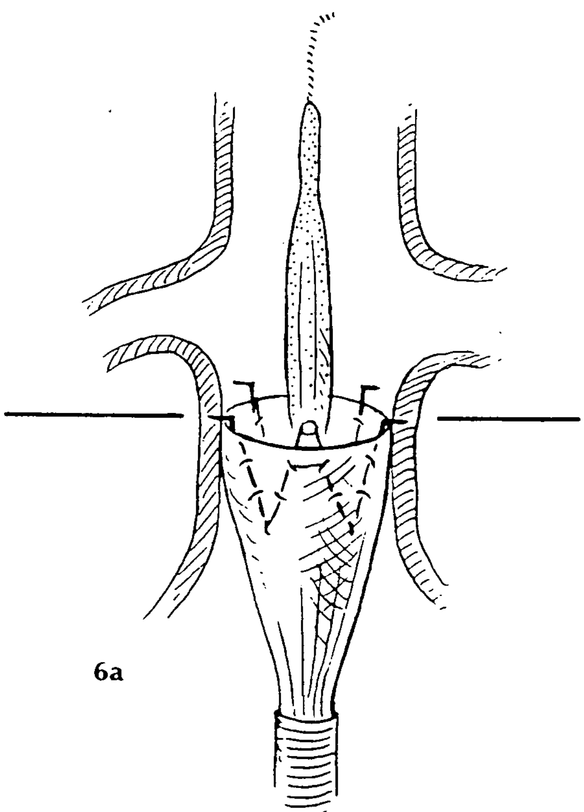


5b

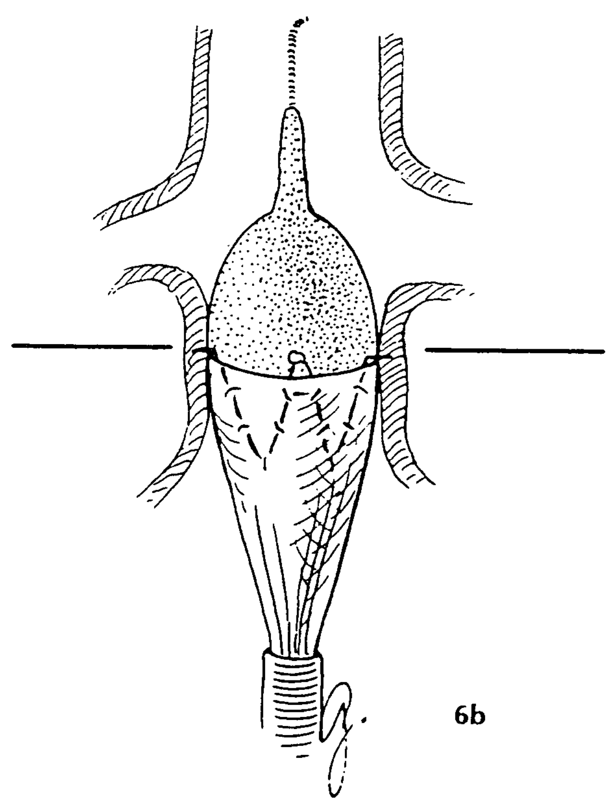
6a & b

The capsule covering the graft is then retracted by turning the knob on the handle of the deployment catheter (*6a*). This is viewed fluoroscopically. Final adjustments are made before the stent on the proximal portion of the graft is allowed to spring open and engage the aorta. Once the operator is certain that the pins on the proximal stent are in the optimal location, final retraction of the sheath takes place, and the graft springs into position.

At this point, the balloon coaxial catheter system is pulled back into position in order to bridge across the proximal stent (*6b*). the balloon is inflated to 2.0 atmospheres of pressure using radio-opaque contrast. The inflation is viewed fluoroscopically within the roadmapped image of the proximal neck of the aorta. The balloon is then deflated, allowing the proximal portion of the graft to fill with pressurized blood. Radio-opaque, longitudinal markers, are then seen to expand along the course of the graft, ensuring that the graft is expanding and that there is no twisting of the prosthesis.



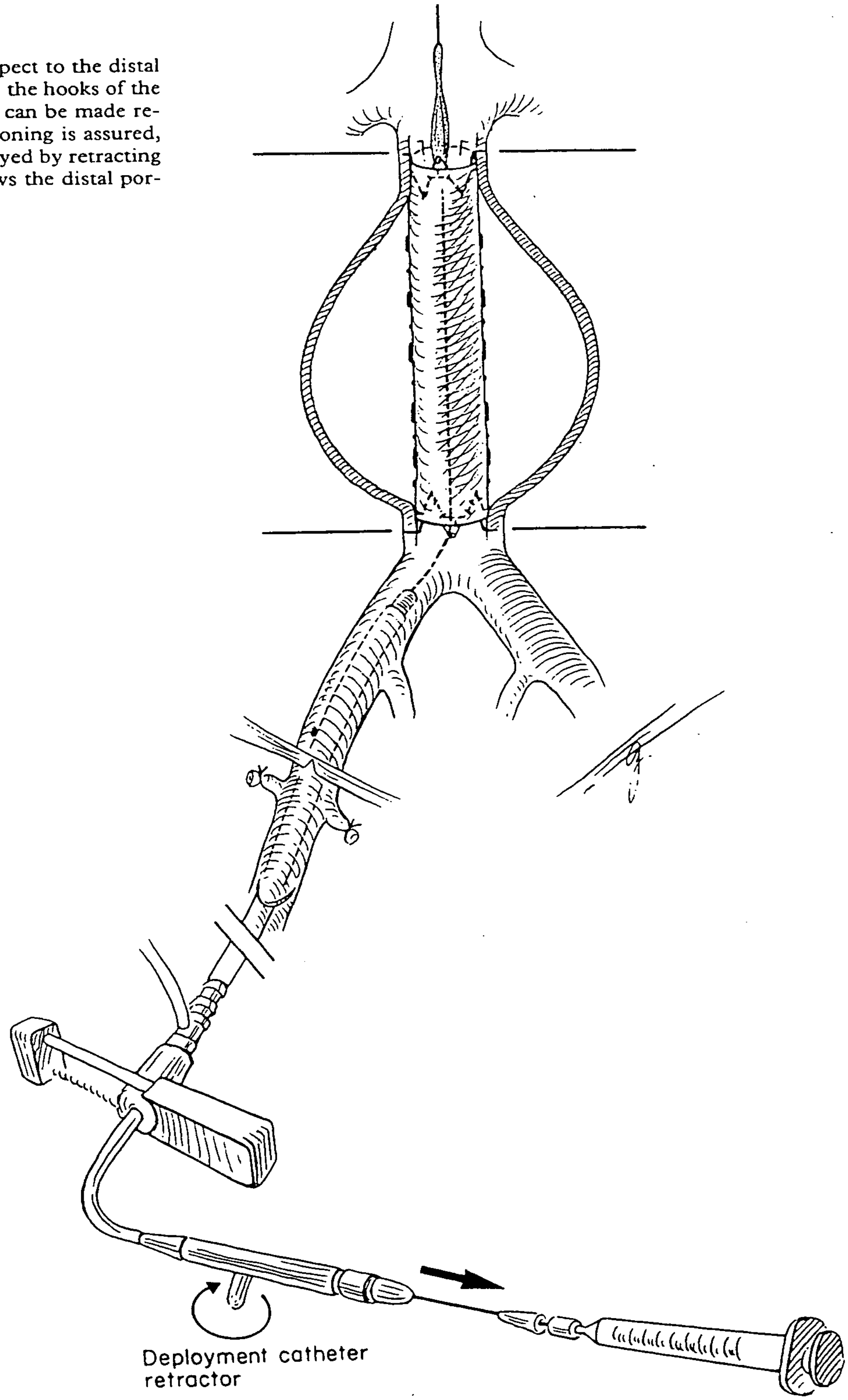
6a



6b

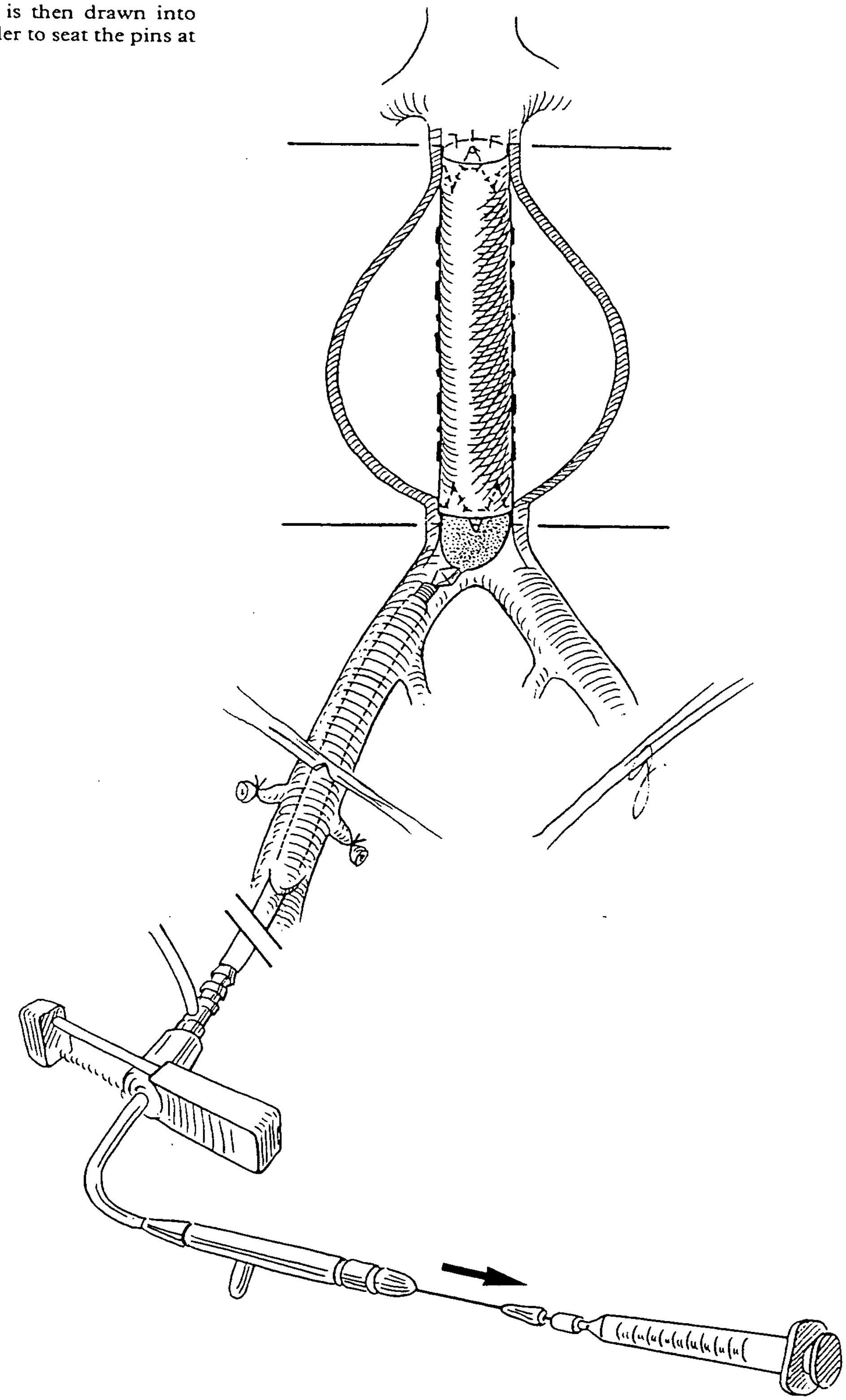
7a & b

Final positioning of the distal stent with respect to the distal cursor line is now possible. If it appears that the hooks of the distal stent are too far distal, an adjustment can be made remotely by the operator. Once optimal positioning is assured, the remaining portion of the capsule is deployed by retracting the catheter delivery system (*7a*). This allows the distal portion of the stented graft to spring into place.



7a

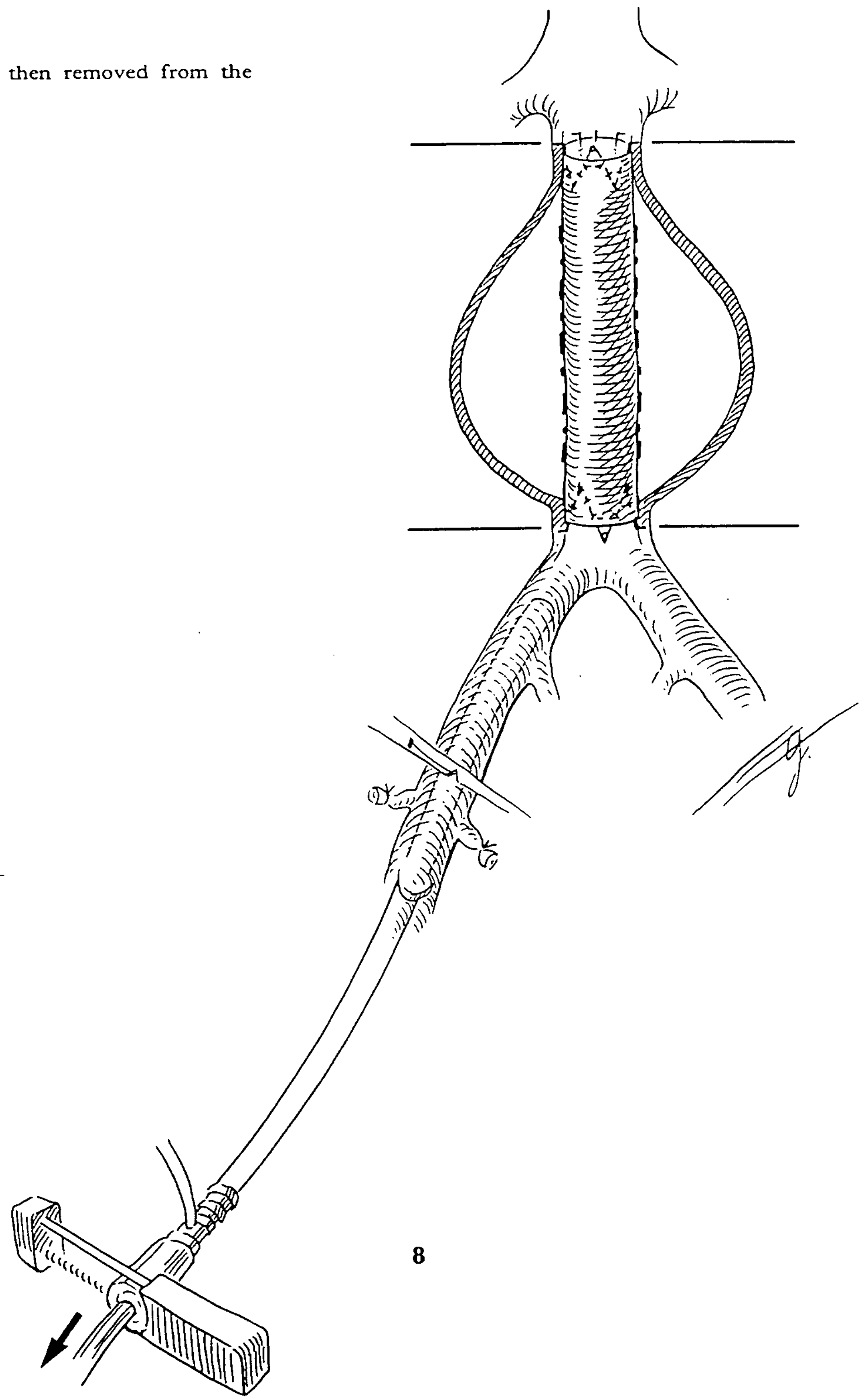
The co-axial balloon catheter system is then drawn into position, and the balloon is inflated in order to seat the pins at the site of distal anastomosis (*7b*).



7b

8

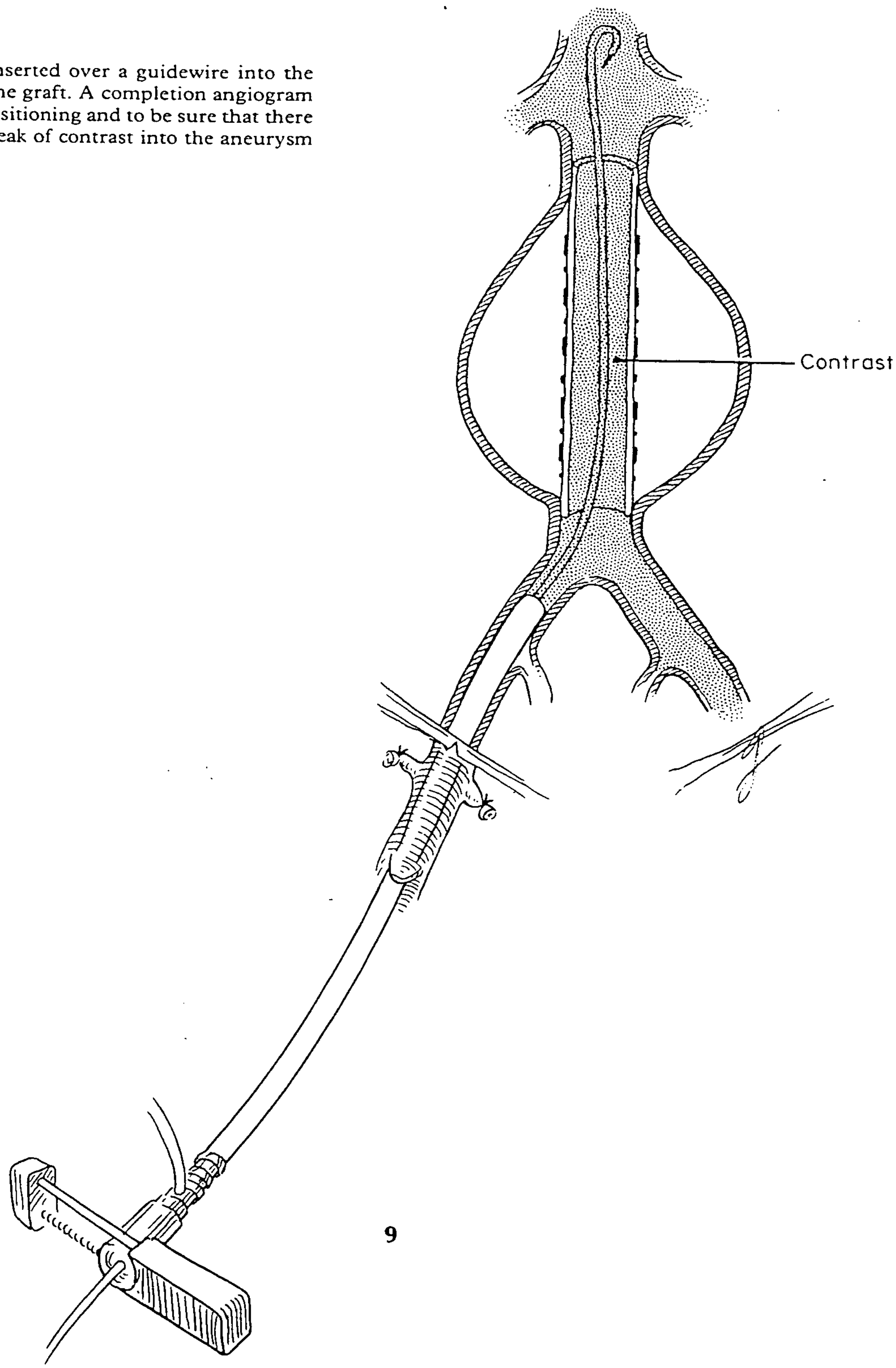
The stent deployment catheter is then removed from the sheath.



8

9

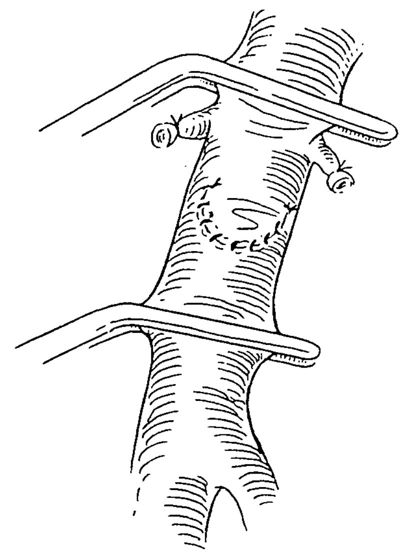
A pigtail catheter is then inserted over a guidewire into the supra-renal aorta through the graft. A completion angiogram is obtained to verify graft positioning and to be sure that there is no evidence of perigraft leak of contrast into the aneurysm at the anastomotic sites.



9

10

Following removal of the sheath, the arterotomy is closed, and flow to the femoral artery is restored.



10

Postoperative care

The patient is allowed to wake up in the recovery room, then transferred to regular ward care. An intensive care unit is not necessary. A regular diet is ordered for the evening, and the patient is discharged from the hospital the following day.

Follow-up studies

Prior to discharge, on the first postoperative day, a plain film of the abdomen is obtained for purposes of visualizing the radio-opaque markers along the course of the graft as well as the radio-opaque proximal and distal stents. This then serves as a baseline. A colour-flow duplex scan of the graft is obtained, documenting flow through the graft and determining whether there is evidence of small leak at either the proximal or distal points of fixation in the aorta. Finally, a CT scan is obtained for baseline purposes. These studies are then repeated periodically for the next 2 years as a part of the protocol.

Several questions remain unanswered and can only be documented with continued observation and follow-up. These include the security of fixation. To date, there has been no tendency of any of the prostheses implanted to migrate. It is important that this continue during the life of the patient and the functioning of the graft. Furthermore, it is not known whether the proximal neck of the aorta will continue to expand and possibly pull away from the sites of fixation. Only time will tell. Finally, there is a risk that a patent inferior mesenteric artery, or perhaps even a lumbar artery, may form an important collateral to mesenteric circulation or that the left colon may be dependent upon blood flow through a patent inferior mesenteric artery. The risk of mesenteric ischaemia exists but has not yet been seen. Finally, it is clear that special training must be obtained before a surgical team can begin implantation. The deployment device is relatively complex, and the series of steps that are necessary for implantation are new and unique in the experience of most surgeons. It may well be desirable for the surgeon to work with an interventional radiologist as a team in the placement of these grafts. However, because of the surgical nature of the procedure, including not only the exposure of the femoral artery but the possible need to immediately convert to an open repair of an abdominal aortic aneurysm, the procedure must be done in the operating room with the surgeon in charge of the team.

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